

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K071216

**1. Submitter
name, address, contact**

Ortho-Clinical Diagnostics, Inc.
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Rochester, New York 14626-5101
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MAY 25 2007

Contact Person: Michael M. Byrne

**2. Preparation
date**

May 1, 2007

**3. Device
name**

Trade or Proprietary Name:
VITROS Chemistry Products CRSC DT Slides
VITROS Chemistry Products DT Calibrator Kit

Common Name: VITROS CRSC assay
Classification Name: Creatinine test system (21 CFR 862.1225).

Common Name: VITROS DT Calibrator Kit
Classification Name: Calibrator (21 CFR 862.1150)

**4. Predicate
device**

The VITROS CRSC assay (modified device) is substantially equivalent to the VITROS CRSC assay (original device). The FDA cleared the VITROS Chemistry Products CRSC DT Slides on and VITROS Chemistry Products DT Calibrator Kit on February 24, 1988 (K875191) under the product names:

KODAK EKTACHEM DT SLIDES (CRSC) and
KODAK EKTACHEM DT Calibrator Kit

Note: With the purchase of KODAK Clinical Products Division by Johnson and Johnson, the product branding was revised to VITROS Chemistry Products CRSC DT Slides and VITROS Chemistry Products DT Calibrator Kit.

The most recent FDA clearance for the VITROS Chemistry Products DT Calibrator Kit was March 21, 1994 (K934071).

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5. Device description

The VITROS CRSC assay is performed using the VITROS Chemistry Products CRSC DT Slides and the VITROS Chemistry Products DT Calibrator Kit on VITROS DT60/DT60II Chemistry Systems.

The VITROS CRSC Slide is a multilayered, analytical element coated on a polyester support.

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Creatinine diffuses to the reagent layer, where it is hydrolyzed to creatine in the rate-determining step. The creatine is converted to sarcosine and urea by creatine amidinohydrolase. The sarcosine, in the presence of sarcosine oxidase, is oxidized to glycine, formaldehyde, and hydrogen peroxide. The final reaction involves the peroxidase-catalyzed oxidation of a leuco dye to produce a colored product.

Following addition of the sample, the slide is incubated. During the initial reaction phase, endogenous creatine in the sample is oxidized. The resulting rate of change in reflection density is proportional to the concentration of creatinine in the sample.

Once a calibration has been performed for each slide lot, creatinine concentration in unknown samples can be determined using the software-resident rate math model and the change in reflectance calculated for each unknown test slide.

VITROS DT Calibrator Kit contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum to which organic analytes, electrolytes, stabilizers, and preservatives have been added. The diluents are prepared from processed water to which inorganic salts have been added. Once reconstituted, the appropriate standards are used to calibrate VITROS DT60/DT60 II Chemistry Systems for the quantitative measurement of creatinine in serum and plasma.

Calibration of the VITROS CRSC assay requires the use of bottles 1, 2 and 4 of the VITROS DT Calibrator Kit.

6. Device intended use

For *in vitro* diagnostic use only.

VITROS Chemistry Products CRSC DT Slides quantitatively measure creatinine concentration in serum and plasma.

For *in vitro* diagnostic use only.

VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl, CO₂, CREA, CRSC, Fe, GGT, GLU, HDLC, K⁺, LAC, LDH, LIPA, Mg, Na⁺, NH₃, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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- 7. Comparison to predicate device** The VITROS CRSC assay (modified device) is substantially equivalent to the predicate, VITROS CRSC assay (original), which was cleared by the FDA (K875191) for *in vitro* diagnostic use.

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Modified Device VITROS CRSC assay (modified)	Predicate Device VITROS CRSC assay (original)
Intended Use	No change	For <i>in vitro</i> diagnostic use only. VITROS CRSC DT Slides quantitatively measure creatinine concentration in serum and plasma. For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl., CO ₂ , CREA, CRSC, Fe, GGT, GLU, HDLC, K+, LAC, LDH, LIPA, Mg, Na+, NH ₃ , PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.
Calibration traceability	The values assigned to the VITROS Chemistry Products DT Calibrator Kit for Creatinine are traceable to a Gas Chromatography Isotope Dilution Mass Spectrometry (GC/IDMS) method ¹ and NIST SRM [®] 914, creatinine standard reference material.	Traceable to Certified NIST (National Institute of Standards and Technology) Reference Material SRM [®] (Standard Reference Material) 914a.
Reference Interval (Serum)	Males: 0.7 – 1.3 mg/dL Females: 0.6 – 1.0 mg/dL	0.8 – 1.5 mg/dL 0.7 – 1.2 mg/dL
Reportable range Serum	0.2-11.2 mg/dL	0.1 – 16.5 mg/dL
Sample type	No change	Serum and Plasma
Basic principle	No change	Colorimetric rate
Instrumentation	No change	VITROS DTSC/DTSCII Module

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- 8. Conclusions** The information presented in the pre-market notification demonstrates that the performance of the VITROS CRSC assay (modified device) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with quality control fluids, proficiency samples, and human serum samples with measured creatinine values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS CRSC assay (modified device) for use with human serum and plasma is safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 2007

Ortho-Clinical Diagnostics, Inc.
c/o Michael M. Byrne, RAC
Regulatory Affairs Associate
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k071216
Trade/Device Name: VITROS Chemistry Products CRSC DT Slides,
VITROS Chemistry Products DT Calibrator Kit
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY, JIX
Dated: May 1, 2007
Received: May 2, 2007

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink that reads "Jean M. Cooper, M.S., D.V.M." The signature is written in a cursive style.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 071216

Device Name: VITROS Chemistry Products CRSC DT Slides

Indications for Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products CRSC DT Slides quantitatively measure creatinine concentration in serum and plasma on the DT60/DT60 II analyzer.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number (if known): K071216

Device Name: VITROS Chemistry Products DT Calibrator Kit

Indications for Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl, CO₂, CREA, CRSC, Fe, GGT, GLU, HDLC, K⁺, LAC, LDH, LIPA, Mg, Na⁺, NH₃, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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